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EXAMINER

KOHARSKI, CHRISTOPHER

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PAPER

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte STEPHEN D. PACETTI

Appeal 2009-013353
Application 09/406,473
Technology Center 3700

Before JENNIFER D. BAHR, MICHAEL W. O'NEILL, and KEN B.
BARRETT, *Administrative Patent Judges*.

O'NEILL, *Administrative Patent Judge*.

DECISION ON APPEAL¹

STATEMENT OF THE CASE

Stephen D. Pacetti (Appellant) appeals under 35 U.S.C. § 134 from the Examiner's Non-Final Office Action mailed September 7, 2006 rejecting claims 142, 143, and 147 under 35 U.S.C. § 103(a) as obvious. Appellant

¹ The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the "MAIL DATE" (paper delivery mode) or the "NOTIFICATION DATE" (electronic delivery mode) shown in the PTOL-90A cover letter attached to this decision.

has cancelled claims 1-141, 144-146, and 148-154. We have jurisdiction under 35 U.S.C. § 6(b).

The Invention

The claims on appeal relate to a sheath adapted to removably cover at least part of an implantable medical device in the form of a balloon which carries a therapeutic substance and which is integrated with a catheter. The sheath has a hollow body and is made of a material capable of preventing the therapeutic substance from significantly absorbing into the sheath. The sheath material is a polymeric material having specific ranges of oxygen transmission rates and water vapor transmission rates at certain parameters (i.e., 0-200 cc/100 in² for 1 mil per 24 hours at 73°F, 75% relative humidity and 1 atmosphere and 0-20 gm/100 in² for 1 mil per 24 hours at 100°F, 90% relative humidity and 1 atmosphere, respectively).

Claims 142, 143, and 147, reproduced below in pertinent part, represent the subject matter on appeal.

142. A sheath comprising

...

wherein the polymeric material comprises a polyurethane having a glass transition temperature above a storage temperature.

143. A sheath comprising

...

wherein the polymeric material comprises a polyurethane having a non-polar soft segment wherein the non-polar soft segment is selected from hydrocarbons, silicones, fluorosilicones, or their mixtures.

147. A sheath comprising

...

wherein the balloon material, sheath material, or both
comprise a therapeutic substance contacting surface,
wherein the therapeutic substance contacting surface
contacts a coating comprising a main-group-element oxide.

The Rejection

The following Examiner's rejection is before us for review:

Claims 142, 143, and 147 are rejected under 35 U.S.C. § 103(a) as
obvious over Sahatjian² (U.S. Patent No. 5,674,192, issued Oct. 7, 1997).

SUMMARY OF THE DECISION

We AFFIRM-IN-PART.

OPINION

Issues

The determinative issues in this appeal are:

- 1) Did the Examiner err in finding it is inherent that polyurethane has a glass transition temperature (T_g) above its storage temperature?
- 2) Did the Examiner err in concluding that based upon the Examiner's finding of common knowledge, one of ordinary skill in the art would modify the non-polar segment of the polyurethane of Sahatjian to be selected from one of the materials recited in claim 143?

² Appellant's June 7, 2007 Appeal Brief and December 5, 2007 Reply Brief both refer to "Sahatjian" and "Sahatjian," but we are assuming that these are typographical errors and that Appellant meant to refer to the correct reference name of "Sahatjian."

3) Did the Examiner err in finding that the sheath material comprises a therapeutic substance contacting surface which is capable of contacting a coating comprising a main-group-element oxide?

Analysis

Issue (1) -- Inherency with respect to Claim 142

Appellant contends that it is not inherent that polyurethane has a glass transition temperature (Tg) above its storage temperature. App. Br. 3. Appellant argues that the Examiner's interpretation that the storage temperature can be any temperature is not reasonable because what one of ordinary skill in the art would understand with respect to the storage temperature should be considered when the Specification fails to specify the storage temperature. App. Br. 3. Appellant also argues that even if the glass transition temperature (Tg) of the sheath material is below the storage temperature, the Examiner's supposition that the sheath would then be liquid or in an unstable form during storage does not necessarily follow. App. Br. 3.

The Examiner's position is that it is inherent that polyurethane has a glass transition temperature (Tg) above its storage temperature. Ans. 3. In an attempt to support that position, the Examiner reasons that since the storage temperature has not been specified in the Specification, "the [storage] temperature can be any temperature." Ans. 4. The Examiner also alleges that if the glass transition temperature (Tg) were above the storage temperature, the sheath would be a solid structure, but if the glass transition

temperature (Tg) were below the storage temperature, “the sheath would be unstable form during storage.”³ Ans. 5.

When relying on the theory of inherency, the examiner has the initial burden of providing a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic reasonably flows from the teachings of the applied prior art. *See In re King*, 801 F.2d 1324, 1327 (Fed. Cir. 1986). This is the case whether the rejection is based on inherency under 35 U.S.C. § 102, prima facie obviousness under 35 U.S.C. § 103, or both jointly or alternatively. *See In re Best*, 562 F.2d 1252, 1255 (CCPA 1977); *see also In re Napier*, 55 F.3d 610, 613 (Fed. Cir. 1995) (“The inherent teaching of a prior art reference, a question of fact, arises both in the context of anticipation and obviousness.”) “In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic *necessarily* flows from the teachings of the applied prior art.” *Ex parte Levy*, 17 USPQ2d 1461, 1464 (BPAI 1990).

We find that the Examiner has not met the initial burden because the Examiner failed to provide a basis in fact and/or technical reasoning to reasonably support the determination that polyurethane inherently has a glass transition temperature (Tg) which is above the storage temperature. Moreover, the allegedly inherent characteristic of polyurethane having a glass transition temperature (Tg) above the storage temperature does not necessarily flow from the teachings of Sahatjian.

³ It is noted that the September 7, 2006 Office Action stated on the bottom of page 2 that “the sheath would be a liquid or unstable form during storage,” and this language was changed to the above-quoted language in the Grounds of Rejection section of the Examiner’s Answer.

Indeed, the Examiner has not provided sufficient evidence to show that one of ordinary skill in the art would understand the claim terminology of “storage temperature” to be any temperature in order to support the Examiner’s broad interpretation. The scope of the claims in patent applications is determined not solely on the basis of the claim language, but upon giving claims “their broadest reasonable interpretation consistent with the specification” and “in light of the specification as it would be interpreted by one of ordinary skill in the art.” *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364 (Fed. Cir. 2004). Thus, even though the storage temperature is not specified in the Specification, it was not reasonable for the Examiner to find that any temperature would suffice. Rather, the Examiner should have considered how the ordinary skilled artisan would have interpreted the claim terminology of “storage temperature.” The Examiner has not justified the broad interpretation of the storage temperature being any temperature and the Examiner’s broad interpretation would effectively read the “storage temperature” limitation out of the claim as being superfluous. *See Stumbo v. Eastman Outdoors, Inc.*, 508 F.3d 1358, 1362 (Fed. Cir. 2007) (denouncing claim constructions which render phrases in claims superfluous). On the record before us, we cannot conclude that the Examiner applied a correct construction of “storage temperature.”

Additionally, the Examiner’s findings that if the glass transition temperature (T_g) were above the storage temperature, the sheath would be a solid structure, and if the glass transition temperature (T_g) were below the storage temperature, the sheath would be a liquid or unstable form during storage, fail to provide a basis in fact and/or technical reasoning to reasonably support the determination that polyurethane inherently has a

glass transition temperature (T_g) which is above the storage temperature. Indeed, the Examiner's findings show an incorrect understanding of the term "glass transition temperature (T_g)" which is not a melting point marking the change from a solid state to a liquid state as occurs in crystalline polymers, but rather is the temperature where amorphous polymers change from being hard and brittle to being soft and pliable. Thus, it does not necessarily follow that if the glass transition temperature (T_g) were below the storage temperature, the sheath material would not be solid or would be unstable.

In view of the foregoing, the Examiner's decision to reject claim 142 under 35 U.S.C. § 103(a) as being obvious over Sahatjian cannot be sustained.

Issue (2) -- Official Notice with respect to Claim 143

The Examiner's position is that "[i]t is common knowledge in the chemical art to modify the non-polar segments in order to provide properties such as flexibility and bendability which are desired in the medical arts.

Ans. 5. From this finding of common knowledge, the Examiner concluded that "it would have been obvious to modify any medically acceptable material to the essential properties, which are desired." Ans. 5.

Appellant contends that even accepting the Examiner's finding of what is common knowledge in the art, one of ordinary skill in the art would not be lead to modify the non-polar segment of the polyurethane of Sahatjian to be selected from the particular materials of hydrocarbons, silicones, fluorosilicones, and mixtures thereof as recited in claim 143. App. Br. 6.

We agree with Appellant that even accepting the Examiner's finding that "[i]t is common knowledge in the chemical art to modify the non-polar segments in order to provide properties such as flexibility and bendability

which are desired in the medical arts,” the Examiner has not established that one of ordinary skill in the art would have been lead to modify the non-polar segment of the polyurethane of Sahatjian to be selected from any one of hydrocarbons, silicones, fluorosilicones, or their mixtures as recited in claim 143. This is because the Examiner’s finding of common knowledge is directed to properties such as flexibility and bendability, but is not directed to the materials which would have been recognized by a person of ordinary skill in the art as having such properties. In other words, the Examiner has not made any finding that materials such as hydrocarbons, silicones, fluorosilicones, or mixtures thereof, would have been recognized by persons of ordinary skill in the art as having properties rendering them suitable for use as the non-polar segment of the polyurethane of Sahatjian.

Based on the foregoing, the Examiner’s decision to reject claim 143 under 35 U.S.C. § 103(a) as being obvious over Sahatjian cannot be sustained.

Issue (3) -- Obviousness of Claim 147

Appellant contends that Sahatjian fails to disclose the claim recitations of “wherein the balloon material, sheath material, or both comprise a therapeutic substance contacting surface,” and “wherein the therapeutic substance contacting surface contacts a coating comprising a main-group-element oxide.” App. Br. 8.

The Examiner’s position is as follows:

The Examiner is considering the limitation of the main group element oxide to not be positively claimed. The sheath material has a contacting surface which is considered by the Examiner to be the inner/internal surface of the sheath. The

Examiner is considering the coating to be on the balloon which is not being positively recited. Thus, it is the Examiner's position that the sheath has a contacting surface which is capable of contacting a balloon which could have a main-group-element oxide.

Ans. 9.

Although the Appellant filed a Reply Brief, Appellant's Reply Brief does not refute the Examiner's above-quoted clarification of the Examiner's position.

We note that Appellant has the burden on appeal to the Board to demonstrate error in the Examiner's position. *See In re Kahn*, 441 F.3d 977, 985-86 (Fed. Cir. 2006) ("On appeal to the Board, an applicant can overcome a rejection [under § 103] by showing insufficient evidence of *prima facie* obviousness or by rebutting the *prima facie* case with evidence of secondary indicia of nonobviousness.") (quoting *In re Rouffet*, 149 F.3d 1350, 1355 (Fed. Cir. 1998)).

More particularly, the Appellant has made arguments with respect to these claims which simply state, in whole or in part, that the references do not disclose or suggest certain claimed features – without responding to the Examiner's reasoning in establishing a *prima facie* case of obviousness. A general allegation that the art does not teach any of the claim limitations is no more than merely pointing out the claim limitations. A statement which merely points out what a claim recites will not be considered an argument for separate patentability of the claim. 37 C.F.R. § 41.37(c)(1)(vii).

Appellant's statements in the Appeal Brief that Sahatjian fails to teach or suggest the limitations of claim 147 are a general allegation that the art

does not teach the claim limitations. We do not find the general allegation to be a convincing argument for separate patentability of the claim.

Based on the foregoing, the Examiner's rejection of claim 147 under 35 U.S.C. §103(a) as being obvious over Sahatjian is sustained.

CONCLUSIONS

The Examiner erred in finding that it is inherent that polyurethane has a glass transition temperature (T_g) above its storage temperature.

The Examiner erred in concluding that one of ordinary skill in the art would have modified the non-polar segment of the polyurethane of Sahatjian to be selected from any one of hydrocarbons, silicones, fluorosilicones, and mixtures thereof in view of the Examiner's finding of common knowledge.

The Examiner did not err in finding that the sheath material comprises a therapeutic substance contacting surface which is capable of contacting a coating comprising a main-group-element oxide.

DECISION

We reverse the Examiner's decision to reject claims 142 and 143 as being obvious under 35 U.S.C. §103(a) over Sahatjian. We affirm the Examiner's rejection of claim 147 as being obvious under 35 U.S.C. §103(a) over Sahatjian.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). *See* 37 C.F.R. § 1.136(a)(1)(iv) (2007).

AFFIRMED-IN-PART

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Application 09/406,473

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